Amendments to the Claims

The following Listing of Claims show the claims as currently amended, and will replace all previous versions in the subject application:

LISTING OF CLAIMS

Claim 1 (currently amended). A pharmaceutical dosage form comprising a pharmaceutical tablet comprising segments, in which a first segment comprises ~~an intrinsically altered release~~ a composition comprising a pharmaceutical agent in a pharmacologically effective quantity, and a second segment comprising:

a) a substantially immediate release composition that lacks a pharmacologically effective quantity of any drug or comprises at least a pharmacologically effective quantity of any drug ~~but not a therapeutically effective quantity of any drug~~, said second segment forming

i) an outer segment that lacks a pharmacologically effective quantity of any drug adjacent to a segment comprising a pharmacologically effective quantity of any drug, or

ii) an inner segment that is adjacent above and below to segments that comprise a pharmacologically effective quantity of any drug wherein the drugs in the above and below segments are physically and chemically compatible with one another ~~or, have substantially only immediate release characteristics~~; or

b) optionally, a score greater than 50% ~~and preferably greater than 70%~~ through the maximum height of said scored segment; or

~~c) intrinsic altered release properties, contains a pharmacologically effective quantity of any drug, and adjoins said first segment or is separated from said first segment by a third segment that~~

~~i) is a composition having substantially immediate release properties, or~~

~~ii) has intrinsic altered release property and comprises a pharmacologically effective quantity of any drug; or~~

~~d~~c) without limitation, a segment of said tablet in which said tablet has a height that is greater than any transverse dimension and

i) lacks a semi-permeable membrane coating, or

ii) lacks an osmotically active component to effect intrinsic altered release, or

iii) lacks a drug over-coating, or

iiii) said first and second segments contain pharmacologically effective quantity of any drug, wherein

the terms for directions such as "above," below", "height" and "transverse dimension" refer to the position of said tablet in a tablet die after tablet compression has been completed but before said tablet has been ejected from said die and tablet compression occurs in a tablet press in which layers are formed vertically, with a second or subsequent layer placed above and contacting a preceding layer.

Claim 2 (canceled).

Claim 3 (original). The dosage form of claim 1 wherein said first segment comprises a therapeutically effective quantity of the pharmaceutical agent.

Claim 4 (original). The dosage form of claim 1 wherein said altered release composition includes, without limitation, such compositions as delayed release, modified release, controlled release, quick dissolve oral, sustained-release, buccal, and those containing solubility modifiers.

Claim 5 (canceled).

Claim 6 (original). The dosage form of claim 1 wherein said second segment is an inner segment and comprises a therapeutically effective quantity of any drug.

Claim 7 (currently amended). The dosage form of claim 1 wherein said first segment is scored greater than 50% ~~and preferably greater than 70%~~ through the maximum height of said segment.

Claim 8 (original). A pharmaceutical tablet comprising a first segment and a second segment, wherein at least one of said segments is formulated for altered release of said drug or drugs, in which:

(a) the tablet is a bilayer tablet and said first segment is scored and comprises a drug or drugs and said second segment is substantially free of a drug or drugs; or

(b) the tablet is a bilayer tablet and said first segment and said second segment include the same drug or drugs formulated as a non-osmotic composition; or

(c) the tablet comprises at least three segments and said first segment and said second segment include the same drug or drugs, said segments being separated by a third segment that is compositionally distinct from said first and second segments; or

(d) the tablet comprises at least three segments and said first segment includes a pharmacologically effective amount of a first drug or drugs, said second segment includes a pharmacologically effective amount of a second drug or drugs and is substantially free of said first drug or drugs, wherein said tablet further comprises a third segment interposed between physically and

chemically compatible first and second segments, said third segment being substantially free of a therapeutically effective amount of said first and second drug or drugs; or,

(c) the tablet comprises at least three segments and said first segment includes a pharmacologically effective amount of a first drug or drugs, said second segment includes a second drug or drugs and is substantially free of a therapeutically effective amount of said first drug or drugs, wherein said tablet further comprises a third segment interposed between physically or chemically incompatible first and second segments, said third segment substantially free of a therapeutically effective amount of said first or second drug or drugs and having a height in excess of a minimum amount required to separate incompatible layers.

Claim 9 (original). The pharmaceutical tablet of claim 1 wherein said first and second segments include the same drug or drugs, said second segment having said drug at a lower concentration than the concentration of said drug or drugs in said first segment.

Claim 10 (original). The pharmaceutical tablet of claim 1 wherein said first segment comprises a first drug or drugs and said second segment comprises the first drug or drugs and a second drug or drugs, wherein said first segment is substantially free of said second drug or drugs.

Claim 11 (original). The pharmaceutical tablet of claim 1 wherein said third segment includes a third drug or drugs and said first and second segments are substantially free of said third drug or drugs.

Claim 12 (currently amended). The pharmaceutical tablet of claim 1 wherein said ~~third~~ second segment has a height greater than the combined height of said first segment and said third segment.

Claim 13 (original). The pharmaceutical tablet of claim 7 comprising a separation mark oriented substantially horizontally on or within a segment to guide tablet breaking through one segment substantially without breaking through another segment, said separation mark selected from the group consisting of a score, perforation, color, printed marking or indicia, gelatin band, or a combination thereof.

Claim 14 (original). The pharmaceutical tablet of claim 7 comprising a score which is at least 70% of the horizontal dimension or width of the segment.

Claim 15 (original). The pharmaceutical tablet of claim 1 wherein the concentration of drug or drugs in said first and second segments is substantially the same.

Claim 16 (original). The pharmaceutical tablet of claim 1 wherein the quantity of drug or drugs in said first and second segments is substantially the same.

Claim 17 (original). The pharmaceutical tablet of claim 1 having a vertical and horizontal axis, said tablet comprising a substantially horizontal separation mark positioned parallel to the vertical axis of the tablet along a side of at least one segment, said vertical axis being directionally the same as the vertical axis of a tablet die in which the tablet is made.

Claim 18 (original). The pharmaceutical tablet of claim 8 having an interposed third segment wherein said first segment and said second segment are compositionally substantially identical.

Claim 19 (original). The pharmaceutical tablet of claim 1 comprising in at least one segment a color for visually distinguishing said segment from another segment.

Claim 20 (original). The pharmaceutical tablet of claim 1 wherein breaking of said tablet through a segment yields a tablette having a predetermined quantity of drug.

Claim 21 (original). The pharmaceutical tablet of claim 20 wherein said breaking of a segment is through an interposed third segment.

Claim 22 (currently amended). A pharmaceutical dosage form comprising a pharmaceutical tablet that comprises a granulation with an altered release composition produced sequentially from a first granulation containing a first active drug or first combination of active drugs, a second granulation that is compositionally substantially different from said first granulation; and a third granulation comprising active drug or drugs, in which:

(a) all granulations in the tablet are physically and chemically compatible and said second granulation substantially lacks any active drug; or

(b) the second granulation lacks any active drug and gives rise to a segment after tablet compression ~~has~~ having an effective height of at least 0.5 mm~~; or~~

~~(c) the second granulation contains a drug present in said first or third granulations in a diminished concentration on a weight/weight basis; or~~

~~(d) the second granulation contains a drug not present in either the first or third granulations~~.

Claim 23 (original). The pharmaceutical tablet of claim 22 wherein said second segment has an effective height of about 1.5 mm to about 3 mm.

Claim 24 (original). The pharmaceutical tablet of claim 22 wherein said second granulation is substantially free of a therapeutically effective amount of a drug.

Claim 25 (original). The pharmaceutical tablet of claim 22 comprising additional granulations compressed to form corresponding additional segments.

Claim 26 (original). The pharmaceutical tablet of claim 22 wherein said second segment comprises a substantially horizontally oriented separation mark selected form a score, indicia, or perforation.

Claim 27 (original). The pharmaceutical tablet of claim 22 wherein breaking through said second segment provides accurate separation of said first segment from said third segment without breakage of said first or third segments.

Claim 28 (original). A pharmaceutical dosage form comprising a pharmaceutical tablet that comprises a granulation with altered release characteristics in which an immediate release granulation forms upon tablet compression an outer (top or bottom) segment.

Claim 29 (original). The pharmaceutical tablet of claim 1 wherein said tablet comprises a structure selected from the group consisting of A-I, A-B, A-a, A-a-B, A-I-A, A-I-a, A-I-B, A-B-A, A-B-C, A-I-B-I-A, A-I-B-I-B, A-I-B-I-C, and A-B-I-C wherein

"A" represents an active segment comprising a first active drug or combination of more than one active drug;

"a" represents a segment comprising the first active drug or drugs at a different concentration than "A";

"B" represents an active segment comprising a second active drug or combination of active drugs;

"C" represents an active segment comprising a third active drug or combination of drugs; and

"I" represents an inactive segment substantially free of active drug or combination of active drugs;

wherein each represented segment is vertically disposed upon another.

Claim 30 (original). A method of breaking a pharmaceutical tablet of claim 1, said method comprising applying pressure to said tablet in order to break through one segment without breaking through another segment adjacent to said one segment.

Claim 31 (original). The method of claim 30, wherein said segment being broken through is a segment substantially free of a drug or combination of drugs.

Claim 32 (original). The method of claim 30, wherein said segment being broken through comprises a separation mark selected form a score, indicia, or perforation.

Claim 33 (original). A method of administering a partial dose of a drug contained in a pharmaceutical tablet of claim 1, said method comprising the steps of breaking said pharmaceutical tablet through one segment to form two or more tablettes and administering at least one of said tablettes to a patient.

Claim 34 (original). The method of claim 33 wherein said one segment is broken through without breaking through an adjacent segment.

Claim 35 (original). The pharmaceutical tablet of claim 1 wherein said tablet is further covered with an inert or pharmaceutically inactive composition.

Claim 36 (original). The pharmaceutical tablet of claim 35, wherein said inert composition covering said tablet comprises a capsule or said tablet is placed within a sachet.

Claim 37 (original). A method of reducing risk or preventing patient confusion in a treatment using a covered tablet of claim 35, said method comprising optionally removing the covering of said covered tablet; breaking the tablet into tablettes; and administering at least one of the tablettes to a patient.

Claim 38 (original). The pharmaceutical tablet of claim 1 comprising a drug or drugs pharmacologically effective in the treatment of a condition, disease or disorder selected from the group consisting of: cardiovascular condition, psychiatric condition, diabetes, thyroid disorder, pain and thrombotic disorder.

Claim 39 (original). A compressed pharmaceutical tablet comprising at least two segments, wherein at least one of said segments comprises a drug or drugs formulated as a controlled release composition, said tablet having a top and a bottom and a height and width, said height measured vertically from the top to

the bottom of said tablet while it is in the tablet die in which it is fully compressed, said width being the greatest horizontal dimension of the tablet at a location about halfway between said top and said bottom of said tablet, said height exceeding a width of said tablet.

Claim 40 (original). The pharmaceutical tablet of claim 1 consisting essentially of a first end segment, a second end segment, and a third segment interposed therebetween, said first and second end segments each occupying no more than 20% of the height of said tablet.

Claim 41 (original). The pharmaceutical tablet of claim 40 wherein said first and second end segments each occupy no more than 10% of the height of said tablet.

Claim 42 (original). A method of breaking a pharmaceutical tablet of claim 39 wherein said tablet is broken through its shortest dimension or dimensions.

Claim 43 (original). The method of claim 39 wherein said tablet is broken through one segment without breaking through a segment adjacent to said one segment.

Claim 44. (original). A method of creating a precise quantity of a drug by breaking through a segment of a pharmaceutical tablet of claim 1.

Claim 45 (currently amended). A compressed pharmaceutical tablet having a first segment comprising a drug or drugs formulated as a controlled release composition, said first segment having a score, said tablet further comprising a second segment, in which:

a) said second segment is substantially free of drug or drugs in said first segment; ~~or~~ and

b) said score in said first segment extends at least 50% ~~and preferably at least 70%~~ of the distance from a top surface of said first segment to an interface of said first and second segments, said distance being measured along a line which is the shortest distance from said surface to the interface.

Claim 46 (original). The pharmaceutical tablet of claim 45 in which the distance is from about 50% up to about 99.5%, and said second segment is substantially free of drug or drugs.

Claim 47 (original). The pharmaceutical tablet of claim 46 wherein said second segment adjoins a third segment at a face of said second segment opposite the interface of said first and second segments.

Claim 48 (canceled).

Claim 49 (original). A method of breaking a pharmaceutical tablet of claim 8 which comprises breaking said tablet through a score in which the score distance is no less than 50% of the height of said scored segment.

Claim 50 (original). The method of claim 49, said method comprising breaking through said first segment through said score and also breaking through said second segment.

Claim 51 (currently amended). A pharmaceutical dosage form of claim 1 comprising a tablet containing metoprolol or pharmaceutically acceptable salt thereof, or a polymorph, pro-drug, or isomer, in which said tablet comprises at least one segment containing metoprolol and has altered release characteristics, and said tablet contains a substantially inactive segment.

Claim 52 (original). A pharmaceutical dosage form as described in claim 51 in which the metoprolol-containing segments are both above and below a substantially inactive immediate release segment.